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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,508	01/29/2007	Sajinder Kaur Luthra	PH0423	5660

36335 7590 09/30/2010

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,508	LUTHRA ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/2/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

The Examiner acknowledges receipt of the amendment file 8/21/10 wherein claims 1-13 were canceled and claims 14-23 were added.

Note: Claims 14-23 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

The Applicant's arguments and/or amendment filed 8/2/10 to the rejection of claims 1-13 made by the Examiner under 35 USC 102, 103, 112, and/or double patenting have been fully considered and deemed persuasive for the reasons set forth below. Therefore, the said rejections are hereby withdrawn.

Double Patenting Rejection

The double patenting rejections are WITHDRAWN because after re-evaluating the claims of both applications, it was deemed that the inventions were not obvious variants of one another.

112 First Paragraph Rejection

The 112 first paragraph rejections are WITHDRAWN because Applicant has canceled claims 1-13.

112 Second Paragraph Rejection

The 112 second paragraphs rejections are WITHDRAWN because Applicant has canceled claims 1-13.

102 Rejection

The 102 rejection is WITHDRAWN because the claims have been amended to incorporate essential method steps that are distinguished over the art cited in the rejection.

103 Rejection

The 103 rejection is WITHDRAWN because the claims have been amended to incorporate essential method steps that are distinguished over the art cited in the rejection.

NEW GROUNDS OF REJECTION

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for radiolabeled products containing 18F, 11C, 131I, 123I, 124I, 122I, or 125I, does not reasonably provide enablement for all radiolabeled products. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in In re Wands (8 USPQ2d 1400 (CAFC

1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to the purification of a radiolabeled product.

(2) State of the prior art

The references of record do not disclose a process of purifying a radiolabeled product as set forth in the instant invention.

(3) Level of one of ordinary skill in the art

Independent claim 14 encompasses a vast number of possible radiolabeled products. Applicant's specification discloses that the purification process is useful with radiolabeled products containing 18F, 11C, 131I, 123I, 124I, 122I, and 125I.

(4) Level of predictability in the art

Determining the various radiolabeled products compatible with the instant invention requires various experimental procedures and without guidance that is applicable to all radiolabeled products, there would be little predictability in performing the claimed invention. For example, in Applicant's definition of the variables R^* and R^{*b}, it is disclosed that the variables are halogenated or radiohalogenated moieties. Hence, if the variables attached to the vector components read on any and all radiolabeled

substances, then undue experimentation is necessary to determine which halogenated moieties are applicable to all/most radiolabeled compounds in general

(5) Amount of direction and guidance provided by the inventor

Applicant's limited guidance does not enable the public to prepare and purify non-halogenated radiolabeled compounds. Hence, there is no enablement for all possible radiolabeled products.

(6) Breadth of claims

The claims are extremely broad due to the vast number of radiolabeled products known to exist.

(7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-23: The claims are ambiguous because it is unclear what reaction by products are being referred to in the claim (see independent claim 14). In particular, it is unclear how the mixture contains reaction by products when a reaction has not occurred. Specifically, step (i) of claim 14 discloses that the reaction mixture is contacted with a solid support scavenger group. The reaction mixture comprises radiolabeled product, excess precursor, and optionally, reaction by product (see step (i) of claim 14). However, one cannot have reaction by product unless a reaction has occurred. Thus, it is unclear whether or not an essential step(s) is/are missing in the claim.

Claims 14-23: The claims as written are ambiguous because it is unclear what radiolabeled product, excluding products labeled with 18F, 11C, 131I, 123I, 124I, 122I, or 125I. In particular, it is unclear what other radiolabeled product(s) Applicant is claiming that are compatible with the instant invention.

COMMENTS/NOTES

It should be noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art

neither anticipates nor renders obvious a process of purifying a radiolabeled product as set forth in independent claim 14.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

September 28, 2010